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August 20, 1999

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville MD 20852

Attention: Robert R. Gatling

RE: Docket No. 99N-1737

"Public Availability of Information on Clinical Trials for Investigational Devices
Intended to Treat Serious or Life-Threatening Conditions; Request for Comments"

Dear Mr. Gatling,

As a developer of novel medical devices, The Innovation Factory (TIF) appreciates the opportunity to comment on the June 22, 1999, *Federal Register* Notice entitled "Public Availability of Information on Clinical Trials for Investigational Devices Intended to Treat Serious or Life-Threatening Conditions".

While TIF understands that FDA is mandated by FDAMA to prepare a report to Congress on this subject, it appears detailed comments may be premature in light of the fact that the data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions, which is required to be established, is not yet a functional system. Once in place, the drug data bank will be an excellent model to use to discuss the pros and cons of a similar data bank for devices.

Despite the lack of experience with a drug data bank, however, TIF would like to offer the following comments in response to the *Federal Register* Notice:

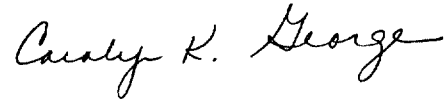
- 1) Sponsors currently have the option of making information regarding their clinical studies publicly available, albeit there is no one single source, or data bank, for this information. There are various existing mediums that can be used to convey study information, should the sponsor choose to employ them. The main questions posed by the Notice are should there be an FDA regulated data bank for devices? And, if so, should participation in the data bank be compulsory or should disclosure continue to be voluntary? As a potential sponsor of

such studies, TIF would prefer to see the status quo continue, where there is no single FDA regulated device data bank and where sponsors can make study information publicly available when and how they choose. If there is an FDA regulated device data bank, participation should be voluntary, regardless of the intended use of the device.

- 2) TIF requests clarification of the contents of the data bank, specifically “a point of contact for those wanting to enroll in the trial”. Does FDA anticipate that the sponsor be/ provide this point of contact? If a sponsor is studying a device intended to be used for life-threatening conditions, might that point of contact receive thousands of responses, from the U.S. and internationally, to this posting? How could a company, especially a small one, responsibly deal with the gamut of individuals given the range of medical conditions, access to trial sites and understanding of study technicalities, e.g. inclusion and exclusion criteria, that could be involved? What would be the sponsor’s liability, legally and morally, if it turns away someone who “wanted to enroll in the trial” and whose condition subsequently worsens?
- 3) In response to Notice Question 4 “If public disclosure were voluntary, would disclosure by one sponsor put pressure on sponsors of similar investigations to disclose the existence of their studies against their better judgment?”, it is hoped that “better judgment” will always prevail. As mentioned previously, public disclosure is an option currently available to sponsors. TIF is not aware of any undue pressure to disclose under current conditions.
- 4) Notice Question 5 states “If disclosure is mandatory, is it likely to hamper innovations and investment in research and development? Would disclosure of these investigational device trials help or hinder research by increasing patient enrollment?” TIF believes R&D would be hampered due to the potential added complexities of having to deal with more individuals (both included and excluded) and longer trials than predicted or than needed to adequately demonstrate safety and effectiveness. Disclosed information would also be available to potential competitors, which may not be in the best interest of the study sponsor. Further, TIF believes there are other effective ways to enroll satisfactory numbers of qualified candidates in clinical studies. Increasing patient enrollment is not necessarily an end in itself. Seeking out individuals who match the inclusion and exclusion criteria in a satisfactory timeframe is often a challenge; however, implementing a mandatory FDA regulated data bank may not be the best solution.

Thank you for the opportunity to comment on this subject. We hope these remarks are useful to FDA in the preparation of its report to Congress. If you need additional information or clarification on these points, please contact me at 770. 935.4404.

Sincerely,

A handwritten signature in black ink, reading "Carolyn K. George". The signature is written in a cursive style with a large, stylized "G" at the end.

Carolyn K. George
Vice President, Clinical and
Regulatory Affairs

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